REMARKS

The Office Action

Claims 28-60 are pending. Claims 28, 32-38, 59, and 60 are under consideration. Claims 28, 32-38, 59, and 60 stand rejected for indefiniteness and lack of written description. Claims 28, 32-38, 59, and 60 stand further rejected for anticipation by Chan et al. (Journal of Virology, 1992 66:5714-5725; hereafter "Chan"), and claims 28, 32, 33, 36-38, 59, and 60 stand further rejected for anticipation by Dillner et al. (International Publication No. WO 90/04790; hereafter "Dillner PCT") and Dillner et al. (U.S. Patent No. 5,629,146; hereafter "Dillner US"). Applicants note that Dillner US is the U.S. National Stage of Dillner PCT. Claims 28, 32-38, 59, and 60 also stand rejected for anticipation by or alternatively for obviousness over Frazer et al. (International Publication No. WO 93/02184; hereafter "Frazer").

Claim Amendments

As discussed by telephone with the Examiner, Applicants hereby wish to change restriction groups. The current claims have therefore been amended to change from Group II to essentially Group VIII as described in the Restriction Requirement mailed on May 9, 2003. Support for the present amendments is found in the claims as originally filed and on page 6, lines 16 – 32, page 7, lines 8 – 18, and the Examples on pages 32-36.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 28, 32-38, 59, and 60 stand rejected for lack of written description. In making this rejection, the Office states that "the claims are broadly drawn to multitude of 'homologous' sequences, functionally active variants thereof, 'compounds', and/or polypeptides of various sizes." The Office further states that the present specification "describes sequence consisting of a sequence identified as SEQ ID NO: 12," and that Applicants "do not describe other molecules encompassed by the claims, and the structural features that distinguish all such proteins from other proteins." (emphasis in original) Applicants traverse this rejection.

Contrary to the Office's assertion, Applicants clearly describe common structural features for the cytotoxic T-cell epitopes employed in the methods recited in the instant claims. Amended claim 28 requires that each cytotoxic T-cell epitope employed therein include the sequence of SEQ ID NO: 12 or be a variant thereof having a cytotoxicity which corresponds to at least the sum of the average of the negative controls and three times the standard deviation in a T-cell cytotoxicity assay system. Suitable T-cell cytotoxicity assay systems are described in Examples 2 – 5 in the specification on pages 32 - 36. Since Applicants have provided a common structural feature for the cytotoxic T-cell epitopes recited and criteria that define suitable variants, the rejection for lack of written description may be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 28, 32-38, 59, and 60 also stand rejected for indefiniteness on a number of grounds. Applicants traverse these rejections as applied to the amended claims.

Claim 28 stands rejected for reciting the phrase "functionally active variant thereof." Applicants have amended claim 28 to specify that the variants are those in "a T-cell cytotoxicity assay system [having] a cytotoxicity which corresponds to at least the sum of the average of the negative controls and three times the standard deviation." Such assays are described in the instant specification, as stated above. Since suitable assays and measurable criteria for identifying variants encompassed by the instant claims are provided, Applicants have defined the metes and bounds of these claims, and the rejection for indefiniteness may be withdrawn. Claim 28 stands further rejected for reciting "having." Applicants have amended claim 28 to replace "having" with "comprising," and this rejection may also be withdrawn.

Claim 32 stands rejected for reciting "compound." The claim has been amended to recite that the "compound comprises said cytotoxic T-cell epitope" to clarify that the "compound" referred to in the claims contains the polypeptide of SEQ ID NO: 12 and is not an unrelated compound such as aspirin. The rejection may be withdrawn.

Claims 33-37 stand rejected because "the intended polypeptide(s) is/are not defined." Applicants have amended claims 34-37 to depend from claim 33 (which itself depends from claim 32), and thus the "polypeptide" recited in these claims refers to one that includes the sequence of SEQ ID NO: 12. The rejection may be withdrawn.

Claims 36 and 59 stand rejected for reciting "approx." The term has been deleted from claim 36 and replaced with "approximately" in claim 59, and the rejection may be withdrawn.

Finally, claims 59 and 60 stand rejected for reciting "homology" and "at least approx. 65%, ... 75%...., 85%" because "it is not clear what sequences are encompassed." Applicants assert that the term "homology" is well known in the art and, as recognized by the Office, techniques for calculating homology are also known in the art. Therefore, one skilled in the art could readily identify those sequences having at least approximately 65% homology to SEQ ID NO: 12, as required in instant claim 59, and those sequences having structural homology to SEQ ID NO: 12, as required in claim 60. In addition, claims 59 and 60 now recite that the "variant [be] obtainable by generating specific T-cells against the T-cell epitopes and assaying for recognition by the peptide-specific T-cells," providing further criteria for identifying appropriate variants. Support for this amendment is found, for example, on page 7, lines 8-18 and Examples 2-5. The rejection for recitation of "homology" may therefore be withdrawn.

Rejections under 35 U.S.C. §§ 102 (b) and 103(a)

Claims 28, 32-38, 59, and 60 stand further rejected for anticipation by Chan and for anticipation by or obviousness over Frazer, and claims 28, 32, 33, 36-38, 59, and 60 stand rejected for anticipation by Dillner PCT and US. To sustain an anticipation rejection, a reference must teach each and every element of the claims (M.P.E.P. § 2131).

In addition, to establish a *prima facie* case of obviousness, the references must teach or suggest each element of the claims (M.P.E.P. § 2143). These standards have not been met in the present case, as applied to the amended claims.

Claim 28, from which all other claims depend, has been amended to recite a "method of causing or detecting a cytotoxic immune response using at least one cytotoxic T-cell epitope comprising an amino acid sequence ICWGNQLFV (SEQ ID NO: 12)." (emphasis added) Applicants assert that none of the cited references teaches or suggests the use of an amino acid sequence including SEQ ID NO: 12 in such a method; indeed, each cited reference is silent regarding a cytotoxic immune response. Since none of the references teach or suggest the use of SEQ ID NO: 12 in a method for causing or detecting a cytotoxic immune response, the anticipation and alternative obviousness rejections should be withdrawn.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. Enclosed is a Petition to extend the period for replying to the Office action for two months, to and including January 6, 2004, and a check in payment of the required extension fee. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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